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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,204	12/21/2000	Helena Seppanen	09910-007001	5981

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EXAMINER

DO, PENSEE T

ART UNIT PAPER NUMBER

1641

DATE MAILED: 08/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/646,204

Applicant(s)

SEPPANEN ET AL.

Examiner

Pensee T. Do

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Amendment Entry & Claim Status

The amendment filed on May 7, 2004 has been acknowledged and entered.

Claims 1-26 are pending.

Maintained Rejection(s)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 7-14, 15, 16, 17, 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hawkins (US 5,705,628) further in view of Smith et al. (US 4,272,510).

Hawkins teaches a method of DNA purification and isolation using magnetic particles. The method comprises of incubating single stranded DNA and magnetic particles in a microtiter plate; Add 100 ul of binding buffer (20% PEG 8000 and 2.5 M NaCl) which corresponds to the surface tension releasing agent in the present invention and mix; magnetically separate the particles and remove the DNA to a new microtiter plate. The magnetic particles used were the carboxyl coated magnetic microparticles which were 1 um in diameter. (see col. 9, lines 20-30; example 4).

However, Hawkins fails to teach using a magnetic probe to separate the magnetic particles from the mixture and transferring the magnetic particles to the next medium.

Smith et al. teaches means for applying magnetic force to move antigen-antibody coated solid phase units from one place to another, i.e. from a predisposed reaction mixture to reaction mixture, into and out of large volumes of rinsing fluids and finally to test tubes or vials which are to be inserted into a gamma counter. The solid phase unit comprises a core of ferrous metal (core of magnetic material).

It would have been obvious to one of ordinary skills in the art to use the magnetic separation device of Smith et al. to separate bound magnetic particles in the method of Hawkins because Hawkins suggests magnetic separation step and transferring the magnetic particles to a second medium/vessel. By using the magnetic separation means of Smith, the magnetic separation step of Hawkins' method would be carried out at a faster pace thus would save much time and effort and the particles can be transferred to as many vessels as possible. Also, by using such combination, a large number of solid phases units (particles) can be separated simultaneously under extreme uniform conditions, so as to yield highly reproducible results in solid phase assays with large numbers of specimen. Regarding the concentration the magnetic particles, it would have been obvious to one of ordinary skill in the art to adjust such concentration to execute optimum binding between the magnetic particle and the target analyte.

Regarding claim 17, one of ordinary skills in the art would find it obvious to add a STRAs in all the mediums through routine experimentation.

Claims 1-6, 9, 13, 14, 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Czerlinski (US 4, 454,234) further in view of Smith et al. (US 4,272,510).

Czerlinski teaches a method for separating magnetic particles. The rabbit anti-BSA antibodies, a given quantity (50 to 100 ul of BSA per 10 ml tube) of BSA-coated magnetic particles are added to a series of tubes. To each tube, a surface tension releasing agent such as a protein of rabbit antiserum diluted in PBS containing 2% (v/v) of normal sheep serum and 0.05% Tween 20 is added. The magnetic particles are collected with a magnet, washed with 4 ml of PBS containing 0.05% Tween 20. They are collected and resuspended a total of three times. (see example 3).

However, Czerlinski fails to teach using a magnetic probe to collect the magnetic particles and transfer them to a second medium.

Smith has been discussed above.

It would have been obvious to one of ordinary skills in the art to use the magnetic separation device of Smith for the magnetic separation step in Czerlinski's method because such as device would accelerate the collection of the magnetic particles and thus would accelerate the speed of the separation step so that results would be obtained at a faster rate since the method of Czerlinski requires that the magnetic particles must be collected and resuspended a total of three times. Regarding the

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concentration of the tenside, one of ordinary skills in the art would be able to arrive at a suitable range through routine experimentation.

Response to Arguments

Applicant's arguments filed on May 7, 2004 have been fully considered but they are not persuasive.

Regarding the 103 rejection by Hawkins in view of Smith, Applicants argue that the reasoning is flawed because it is not supported by the cited references. Applicants mention that Hawkins discloses a magnetic separation technique and Hawkins does not indicate any deficiencies with its technique. Thus, Applicants submit that one in the art would not look elsewhere for another magnetic separation technique because Hawkins has provided a suitable technique. Applicants also submit that because the particle size of the magnetic particles used in Smith and Hawkins are different, one in the art would not be motivated to use the magnetic probe in Smith for the method of Hawkins.

While Hawkins does not disclose any deficiencies in their disclosed method, the magnetic separation device of Smith et al. provides the advantages set forth in the above rejection and thus would motivate the skilled artisan to use the magnetic separation device of Smith et al. in the method of Hawkins. Smith is relied upon for teaching the means for transferring the target analyte to a second medium. Thus, one of ordinary skill in the art would rely on Smith for the means to transfer the analyte to the second medium. The use of multiple vessels in combination of the magnetic probes in Smith together comprises of a useful device for the magnetic separation method of Hawkins because Hawkins teaches transferring the target molecule to a new microtiter

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or vessel. With the combination of the magnetic probe and the second or third vessels being readily available, the transfer is operated simultaneously and at a faster pace.

Regarding the particle size, Applicants reason that since Smith uses larger particles having diameter range from about 0.1 mm to about 2.0 cm, the relatively heavy macroscopic particles will tend to fall readily to the bottom, while microscopic particles move freely to form suspensions such that separation with a magnetic probe would be quite different. Since the magnetic probe in Smith can attract much larger particles that are at the bottom of the vessel, there would not be any problem attracting smaller particles, which move freely to form suspension in the vessel. Rather, the magnetic probe of Smith must have stronger magnetic strength in order to attract large particles. Thus, with such strong magnetic strength when used to attract the smaller particles such as those in Hawkins, the magnetic probe would attract all the magnetic particles in the medium and thus all the target substance would be transferred.

Regarding the rejection by Czerlinski in view of Smith, Applicants submit that nothing in Czerlinski suggests that its technique requires three suspensions and that the Examiner has taken Czerlinski's examples, which Czerlinski has indicated as "illustrative", to create motivation to combine the references. Nothing in Czerlinski or Smith indicates that one technique is faster than the other. Insofar as Smith describes using multiple vessels simultaneously, the technique of Czerlinski can also be adapted to be used simultaneously with multiple vessels and without using Smith's magnetic probe. The rejection is based on improper hindsight reasoning.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). The illustrative examples of Czerlinski are relating to the preparation and use of the magnetic particles of Czerlinski's invention. Thus, the teaching in Czerlinski that the technique requires three suspensions is within the level of ordinary skill in the art. If the technique of Czerlinski requires three suspensions then the device of Smith would help performing these suspensions at a faster pace because of the combination of the magnetic probe and the multiple vessels. Since the magnetic particles can be collected and resuspended three times in Czerlinski, using combination of the multiple vessels and the magnetic probe in Smith would accelerate the steps of collection and resuspension simultaneously. Afterall, the motivation takes into account only knowledge which was made within the level of ordinary skill, and does not include knowledge gleaned from the applicants' disclosure.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Pensee T. Do
Patent Examiner
August 13, 2004

Christopher L. Chin

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PRIMARY EXAMINER
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8/13/04